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16. ABSTRACT

The various activities involving a chemical (manufacturing, processing, use, distribution in commerce, and disposal) and how the activities lead to exposure are described. Environmental releases from these activities are estimated and integrated with chemical and environmental data, sometimes through mathematical modelling, to determine whether there is a potential for occupational, consumer, or general population exposure.

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APPROACHES TO EXPOSURE ASSESSMENT

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OFFICE OF TOXIC SUBSTANCES
Washington, D.C. 20460

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
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A. Introduction

This Support Document describes the factors involved in performing human exposure assessments in connection with TSCA §4. Each activity involving chemicals (manufacture, distribution in commerce, processing, use, and disposal) and how they relate to exposure are discussed. In addition, the primary sources of information used by EPA for these assessments are listed where applicable. These reference lists are in no way exhaustive. They are merely common basic references which give general information regarding uses, production methods, physical and chemical properties, etc., about each chemical and serve as starting points in the assessment process.

The exposure assessment helps determine whether or not the substance presents a hazard, identifies who should be responsible for testing, and contributes to the design of the test. As discussed in the preamble to the first test rule, the Administrator must make certain findings to require testing of a chemical substance in which exposure is taken into account. The first finding under section 4(a)(1)(A) is "that either the manufacture, distribution in commerce, processing, use, or disposal of a chemical, or any combination of these activities involving the chemical, may present an unreasonable risk of injury to health or the environment." Instead of making the set of 4(a)(1)(A) findings, the Administrator may make findings under §4(a)(1)(B), where EPA may find that a chemical is or will be produced in substantial quantities and that there is or may be significant or substantial human exposure or that the chemical enters or may reasonably be expected to enter the environment in substantial quantities. Two factors are involved in making the §4(a)(1)(A) finding. One is that it is necessary to show that there are grounds to suspect that the chemical may cause adverse environmental or human health effects. The other factor is that any of the activities listed above could present a possibility of

exposure to the chemical. This is because even the most toxic (or oncogenic, teratogenic, etc.) chemicals may not present a hazard if there is no exposure to them. In making the §4(a)(1)(B) finding, only exposure and production need be considered. Therefore, in either case, it is necessary to perform an exposure assessment on a chemical being considered for a §4 test rule. To accomplish this, EPA includes a section entitled Exposure Aspects in each of the chemical specific chapters of the support documents. This section presents pertinent information for determining if there is or could reasonably be expected to be human exposure to the subject chemical associated with any of the activities listed above. In subsequent rules proposing testing for ecological effects, information will be presented relating to potential environmental exposure.

Only manufacturers and/or processors can be required to perform testing of a chemical under TSCA. The designation of whether manufacturers or processors or both should test is based upon an assessment by the Agency of the activities most likely to present a risk. In order to do this, the exposure assessment identifies not only that there is the potential for exposure, but the sources of the exposure as well. For example, the assessment may show that the majority of exposures (or most severe exposures) occur as a result of releases of the subject chemical to the atmosphere during its manufacture. In this case, the manufacturers would be required to perform testing. Thus, the exposure assessment is instrumental in determining whether manufacturers or processors (or both) will be required to test.

Exposure assessments have a third significant role for determining testing requirements--identification of the best route of application. In other words, each assessment will identify whether the greatest amount of exposure occurs through

inhalation, ingestion, or dermal contact. If a chemical is released to the air, inhalation may be the most important route. Similarly, because most solvents evaporate after use (e.g. paints, glues, inks), inhalation might be a most important route of exposure to a chemical which is used largely in or as a solvent. If, however, a solvent such as a cleaning fluid was used by wetting a rag with it and applying it to the surface to be cleaned, the most likely route of exposure would be dermal contact. Clearly if testing is to be required, the results would be most useful if the method of administration of the test substance corresponds to the principal route of exposure that actually occurs in the real world. Therefore, the exposure assessment will also help guide the choice of the route of application required in testing.

In performing an exposure assessment, EPA has recognized that there are essentially two types of pathways a chemical may follow before there is any human exposure. The first type of exposure, sometimes called direct exposure, occurs as an immediate consequence of manufacturing, processing, distribution in commerce, use, and disposal. This type is itself divided into two categories: occupational exposure and consumer exposure. An example of occupational exposure is a worker inhaling chemical fumes in the course of performing his or her job. An example of consumer exposure is a person inhaling fumes while using a product containing the subject chemical. In these cases, the path of the chemical substance may be traced directly from its occurrence to the exposure.

The other type of exposure may be more difficult to trace. It involves the substance entering the environment from one (or more) of the five activities (manufacture, processing, distribution in commerce, use, disposal) and ultimately reaching the general population through its presence in some medium such as air, water, soil, or the food chain. Because the pathway the chemical follows between its release and the exposed individual is indirect, it is sometimes called indirect exposure. However, the test rule support documents refer to it as general population

exposure. An example of this type of exposure is when a chemical is discharged into a river and absorbed by fish. Human exposure would occur through the consumption of the contaminated fish.

Ideally, all three types of exposure (occupational, consumer, general population) would be described quantitatively with respect to the level and duration of human contact with the substance, as well as with the route of exposure (inhalation, absorption, or ingestion). While not necessary for §4 purposes, monitoring data, which show the quantity of a chemical at a particular location at a specific point in time, could be used for this type of assessment. While such monitoring data are available in some situations, they are not generally available for most of the possible circumstances of exposure. Reliance is, therefore, generally placed upon qualitative descriptions of the pathways leading to human exposure, incorporating quantitative data (such as production volume and use) and physical/chemical properties (such as vapor pressure, solubility, and octanol/water partition coefficient). A more complete description of this process may be found in the text of this document.

The information presented in the Exposure Aspects section of each chemical specific support document falls into four general areas: (1) information on the identity of the substance, including its chemical and physical properties; (2) information on the substance's production volume and methods, its industrial, commercial and consumer uses, its distribution in commerce, and its disposal; (3) assessment of occupational and consumer exposure; and (4) assessment of general population exposure, including the known and expected environmental transport and transformations of the substance, its bioaccumulation potential, and monitoring data when available. The nature of the information presented in each of these areas and the sources of that information are discussed in the remainder of this document.

B. Chemical Identity and Properties

Chemical identity information includes the substance's chemical name, synonyms, and trade names. The support document does not present an exhaustive list of the names that are or have been used for the substance. Rather, the most frequently used names are given. In some instances where the chemical name is unwieldy, the Agency has selected a common name or abbreviation to use throughout the support document.

The basic physical properties of interest to EPA are presented (when available) in this section, such as the substance's physical state (that is, whether it is a gas, solid, or liquid) at atmospheric temperature and pressure, its color and odor, its density or specific gravity, boiling point, melting point, vapor pressure, solubility in water and other solvents, its octanol/water partition coefficient, and sorption data. These properties allow EPA to make certain suppositions about the pathway through the environment and the mode of human exposure that might occur. For example, if the substance has a high vapor pressure (evaporates readily), it can be inferred that some exposure by inhalation would be likely to occur if the manufacture, processing, distribution, use, or disposal of the substance is performed in other than completely closed systems. The octanol/water partition coefficient shows the equilibrium distribution of the subject chemical between two liquid phases; n-octanol and water. It is the ratio of the concentration in the octanol phase to that in the water phase and indicates how readily the substance may be absorbed by fatty tissue. If a substance has a high octanol/water partition coefficient, there is a high potential for it to accumulate in fatty tissue. Therefore, it may accumulate in fish or other organisms that are used as a food source.

The chemical and physical properties presented as part of the chemical identity discussion are not, however, the only properties which may have implications for exposure to the substance. More specific information on the properties and reactivities of the substance that affect its behavior in the

environment (e.g., soil adsorption, rate of hydrolysis, photochemistry) will be considered by the Agency where relevant and available and will be included in the discussion of the chemical's environmental fate and transport.

Where the subject is a category of substances rather than a single substance, the chemical identity discussion will include a definition of the category and presentation of information on the properties of specific members of the category where such information is available.

With regard to mixtures, the composition of each will be described as completely as possible, and the properties of the mixture are presented. Where appropriate, information will also be presented on the properties of some or all of the components of the mixture.

This section also discusses the differences that might exist between the "pure" chemical and the substance as it appears in commerce, including the identity of any impurities or intentional additives. This information contributes to EPA's decision on what grade or form of the chemical to be used in testing.

The primary sources of the information presented in the chemical identity discussion include several references, such as the Merck Index, the Handbook of Chemistry and Physics, the Condensed Chemical Dictionary, manufacturer's product information bulletins, and studies appearing in the published literature.

The consideration of all commercial and consumer activities involving the substance provides EPA with information for identifying locations where the substance may be released to the environment as well as potential locations and modes of human exposure. The following sections describe these activities and how they relate to exposure.

C. General Information

This section describes the five activities listed by TSCA and how they are related to human exposure. The type of information needed about each activity and how it is incorporated into an exposure assessment is discussed.

1. Manufacture

The manufacture of the substance or mixture is the initial stage in its progress (transport) through commerce, and it presents the first opportunity for both direct human exposure and release of the material into the environment. There are several pieces of production-related information that are of particular importance in assessing potential exposure to the substance. One of the key items is the quantity of the substance that is manufactured and/or imported annually because this information may indicate the extent of the use of the substance as well as the potential for exposure. Production volumes for the most recent years are considered by EPA whenever possible so that both the average volume of material produced and any trends in production can be discerned. The trends can indicate whether or not a chemical may present a greater risk of exposure in the future. It may be useful to know if production is constant for the year or varies seasonally because exposure potential may vary accordingly. Published information on the number of firms producing the substance, and the number of production plants in operation and their locations is also presented when available. This information could show if exposure could occur locally, regionally, or nationally. Sales figures are also very important because when compared to production volume, they can indicate where exposures may occur. In other words, if a chemical has a large production volume but a low sales volume, it generally means that most of it is consumed within the producing plant. This chemical is then said to have high captive use. This means that occupational exposure may be more significant than other types of exposure.

The major sources of production data used in the support documents are the U.S. International Trade Commission (U.S.I.T.C.) reports on United States sales and production of synthetic and organic chemicals and the TSCA Chemical Inventory. The U.S.I.T.C. reports present, with certain exceptions, the annual volumes of chemicals produced or sold in quantities of 5,000 pounds or more or having a sales value exceeding $5,000 and having at least three manufacturers. The exceptions are plastics and resin materials (which must have production and sales minimums of 50,000 pounds or $50,000 respectively) and pigments, medicinal chemicals, flavor and perfume materials, rubber-processing chemicals, and elastomers with minimums of 1,000 pounds or $1,000. Other sources of production data include various trade publications such as the Chemical Marketing Reporter, Chemical Week, and Chemical and Engineering News.

It is also important to know the form in which the substance is produced as well as the intermediate forms which appear during manufacture. It is possible that the potential for exposure and the route of exposure could change at various points during the manufacturing process as the chemical changes form (e.g., condensation or vaporization of the chemical).

Whenever possible, the processes used to manufacture the substance or mixture are considered by EPA and described in the support document. Information on the production process can provide some insight into the potential for direct worker exposure and for release of the substance to the environment. The number and type of reactors, reaction conditions, and operating procedures are very useful pieces of information in assessing occupational exposure and possible general population and environmental exposure from releases of the substance. Basically, there are three types of chemical reactors used in the chemical industry, known as batch, semi-batch, and continuous flow reactors. A manufacturing (or processing) plant may be composed of one reactor of any type or a number of reactors in any combination of types, depending on the reactions to be

carried out, the reaction conditions (temperature, pressure, etc.), and the quantity of material involved. In a batch reactor, a charge of reactants is added, brought to reaction temperature and pressure, and held at these conditions for a specified length of time after which the product is removed. A semi-batch reactor differs from a batch reactor in that at least one of the reactants is added continuously during the reaction. This is done so that a desired concentration of one of the reactants may be maintained at all times. This is important when it is desirable to obtain a predominant amount of one of several possible products. In a continuous flow reactor, there is a continuous, steady flow of reactants in and products out. In this case, the extent of the reaction (and therefore the composition of the material in the reactor) varies with the position in the reactor. In the batch and semi-batch processes, the extent of reaction varies with time. When flexible operating conditions are required and production is to be on a small scale, the batch-type process is often the most suitable (Smith, 1970). In situations where the production volume is large and more stable reaction conditions are required, the continuous-flow process is more practical.

Chemical plants generally operate with periodic shutdowns for discharging, cleanout, and/or reactivation. This is particularly true with batch reactors or in situations when the rate of production decreases with time because of scaling, reduction of efficiency or collection of a side product, etc. During the shutdown, the reactors may be vented and it is often necessary for workers to enter the reactor vessel to perform the cleaning operation. Thus, there is a risk of exposure to the reactants, contaminants and/or product left in the reactor.

Sampling operations also present opportunities for exposure. This is one of the most common daily operations in the chemical industry (Lovelace, 1979). Sampling is done to establish a material balance (an accounting of materials entering, exiting, and accumulating in a system), evaluate the operation of

a piece of equipment, assist in trouble shooting, or to aid in quality control. The diverse conditions under which samples must be obtained often complicate the sampling technique and put the person taking the sample at risk of exposure to the chemical. When a sample is taken, some amount of material is actually removed from the process. This means that a normally closed system must be opened at some point to allow the removal of the sample. Unless sampling equipment and procedures are carefully designed, some material could escape and endanger the sampling personnel as well as surrounding workers (Lovelace 1979).

When a process is operated at an elevated pressure, it is necessary to provide protective devices such as relief valves or rupture discs to prevent the pressure from increasing to the point of damaging the reactor vessel (Perry et al. 1969). This is also true for storage tanks in which volatile materials are stored. Pressure buildup could occur as a result of its exposure to an unexpected heat source (such as fire), the malfunction of a component of the control system, or perhaps from a change in atmospheric pressure. When the overpressure condition occurs, it is relieved by the release of reactor contents through the relief valves or rupture discs. Thus, anyone in the vicinity of the venting operation is at risk of being directly exposed. In addition, such an event would add to general population exposure.

Within the chemical plant, the reactants and products are transported to and from reactor vessels by various means. Liquids and gases are handled by pumps, compressors, and blowers and are transported in pipes, flumes, and ducts. Solids may be transported by conveyors and lifts. If the conveyor is open to the atmosphere, exposure to a chemical may occur as a result of sublimation or in the form of a dust. In the case of a liquid or gas being transported in a pipe, exposures occur as a result of leaks from piping connections or from cracks or ruptures. Cracks and ruptures occur because of ineffective supports, neglected vibration effects, poor weld quality, and less inspection due to inaccessibility of inside surfaces. Large welded branch con-

nections introduce distortions and possibilities for undetected cracks or flaws as a result of difficult fitting and nonuniform weld stress. Since pipe structures are restrained against movement, the operation of the plant may cause stresses to build up due to vibration, thermal expansion and contraction, etc. As a result, slight deformations may occur which can result in flange leaks, cracks and possibly ruptures (Perry et al. 1969). It should be noted that leaks (also called fugitive emissions) often occur in the absence of the conditions just decribed. Pumps can leak material at the point of contact between the moving shaft and the pump casing. Leaks may also occur in stirred-tank reactors at the point where the agitator (mixer) enters the reactor. Thus, the use of a closed system to manufacture or process a chemical does not insure that there is no exposure to the chemical from its manufacture or processing.

The chemical industry presents a wide range of hazards due to the presence of large quantities of hazardous (toxic, flammable, explosive, corrosive, etc.) substances, frequently at elevated temperatures and pressures which promote ignition or decomposition.

Information on the production process may be available from any of several sources, including reference works such as Faith, Keyes, and Clark's Industrial Chemicals, company product information bulletins, trade publications such as the Chemical Marketing Reporter, the Kirk-Othmer Encyclopedia of Chemical Technology, and occasionally from government reports. Usually, the industial process information available in these sources is not very detailed, owing to the proprietary nature of much of this type of information.

2. Distribution in Commerce

This activity involves the flow or travel of the substance between the other four activities (manufacture, processing, use, and disposal). It may involve the transportation of the substance from the manufacturer to a processor or from a processor

to another processor or to users or from a user to its disposal site. Material balances would show the volumes of chemical substance flowing to and from each activity. Detailed information of this type is difficult to obtain, but EPA is in the process of developing material balances for a number of chemicals. These balances, when available, and the methods developed in them will help provide the information needed to describe this activity in greater detail.

The methods of transportation are also an important consideration in this section since environmental releases may occur as a result of this activity. The type of information available on this subject is typically limited to descriptions of the principal modes of transportation and/or delivery of the material. For example some chemicals are shipped as liquids or gases in tank cars, barges, or trucks, others are transported as solids packed in bags, drums or railroad cars and some may be transported as liquids or gases in pipelines. Exposure to various chemicals occurs as a result of pipeline leaks or ruptures, train derailments, and tank truck accidents. Release data on these incidents are not always available. In addition, the data may be of limited use in predicting the extent of potential exposure or the segment of population at risk because the releases occur as a result of accidents and their magnitude and locations are unpredictable. However, potential for exposure does exist because trains, trucks, and pipelines carrying toxic chemicals travel through populated areas and some form of probabilistic approach to predicting the frequency and magnitude of spills can sometimes be made. It must be realized, though, that such predictions can be misleading. The calculated probabilities may not accurately reflect what actually occurs. A low probability may indicate that there is little or no danger of an accident occurring, but accidents do occur and may have serious local consequences. For example, in recent years, a number of derailments have occurred causing releases of chlorine gas, ammonia, and other toxic chemicals, necessitating the evacuation of the populations in the vicinity of the accidents. Releases which occur during the

loading and unloading operations may be more constant and predictable since these are continuous operations which require the transfer of the substance from one container to another. This sort of release data is, therefore, useful for predicting potential exposure. Some data of this type may be available in NIOSH criteria documents or the National Occupational Hazard Survey, but these sources are limited.

3. Processing

TSCA defines processing as the preparation of a chemical substance or mixture, after its manufacture, for its distribution in commerce [TSCA §3(10)]. The substance may be refined, purified, mixed with other substances repackaged, molded, etc. In the case where the subject chemical reacts with another chemical or catalyst to form another substance, the amount of chemical reacted is no longer of concern. The final product, however, may still be of some concern if it contains residual amounts of the subject chemical. In many cases published reports are available which show the products and quantities derived from the subject chemical substance.

Many processing operations are very similar to the manufacturing operations described in Section 1. That is to say, the same type of equipment is used, the processes involved are similar, and therefore, exposure may occur in the same ways. However, there are a number of operations which are used in the processing of a chemical which may not occur during manufacturing. Some of these are listed in the first paragraph, such as repackaging and molding. It is not the purpose of this document to give an exhaustive list of all processing operations, but in actual practice each processor may use different equipment, methods and procedures, all of which may present different exposure potentials. Therefore, in order to assess exposure most accurately, detailed knowledge of processing operations is helpful. When available, information on the processing operation is presented in this section. However, due to the proprietary

nature of this type of information, process details are often not available.

4. Uses

The uses of a substance are often the key stage in its progress through commerce in determining the potential for direct human exposure. In the Exposure Aspects section of each support document, the Agency attempts to describe as completely as possible the use patterns of the substances under study. Qualitative descriptions of the function of the substance in the products containing it and the specific applications of those products are given whenever such information is available, as are quantitative data on the amount of the substance that goes to each use annually, and the fraction of annual production accounted for by that use.

Use information is particularly valuable to the Agency for determining whether there are certain populations, subpopulations or environmental media that might be subject to significant exposure--such as machine workers exposed to lubricants containing the subject chemical or consumers exposed to the subject chemical as a result of its incorporation into a cleaning product. Of particular interest are uses which expose large populations to the chemical on a continuous or frequent basis, such as cleaning solvents, aerosol propellents, motor fuels, and dyes.

Chemical use information is also valuable for providing an indication of points where the substance may be dispersed into the general environment. For example, chemicals which are used in the textile industry for the dying process may be washed out of the textile upon completion of the dyeing process and discharged into a nearby river which is a drinking water source for downstream human populations. It may be possible to measure the amount of chemical discharged into the river, determine its concentration at the points where the water is withdrawn to serve

towns or cities and combine the data with population measurements to estimate the levels of human exposure.

Another aspect of industrial use is when the subject chemical substance is transformed into another. Examples of this are the manufacture of benzene from toluene or the use of 1,2,4-trichlorobenzene to manufacture the herbicide 2,5-dichlorobenzoic acid. In these types of situations, the quantity of substance available for general population exposure decreases. However, there is still concern about the substance if it is present in emissions from the processing plant or as an impurity in the final product.

In the case of uses involving consumer products, if an estimate can be made of the volume of product consumed, the quantity of chemical contained in the product, and the number of people using the product, the levels of exposure through this route may be estimated.

The major sources of information on uses include various trade publications (again notably the Chemical Marketing Reporter, Chemical and Engineering News, and Chemical Week), reference works such as the Condensed Chemical Dictionary, and Faith, Keyes and Clark's Industrial Chemicals, and company data sheets, when available, and the TSCA Chemical Inventory.

5. Disposal

The disposal of products and industrial wastes containing the subject chemical substance is important with respect to general population exposure and especially important in the analysis of environmental exposure. For example, a tremendous amount of industrial and consumer wastes are placed in landfills every year. Over a period of time, chemicals may leach out of the landfill into groundwater which may flow to wells and be consumed by humans, used on crops, or end up in surface water ecosystems. EPA has published studies which show that this may occur (for example Robertson et al. (1974)). The difficulty with the data from landfill studies is that the leaching process may

change over time, so that the groundwater concentration of the subject chemical may change, and therefore exposure may vary with time. Secondly, the study may only identify a chemical without measuring the quantity present. However, these studies do show the existence of some chemicals in groundwater as a result of landfills. Therefore a rough estimate of human exposure may be possible in many cases.

Other types of disposal methods include wastewater treatment plants and incinerators of various designs and efficiences, deepwell injection, encapsulation and solidification. Studies may sometimes be available on these methods as well. It is useful to know if the substance is disposed through a municipal treatment plant or one exclusively designed and operated by the industry responsible for the discharge. If the treatment plant is operated exclusively by the industry, it may be more efficient in removing certain substances than a municipal plant because it was designed specifically to remove them. However, these studies also primarily identify the effluents from the disposal plant. Detailed data on the influents are not always available. In fact, there is very little information available showing the methods of disposal of many chemicals. The major information sources are government reports and other published literature.

D. Direct Exposure

1. Occupational

The third general area addressed in the Exposure Aspects sections is that concerning direct exposure to the substance or mixture in occupational settings (from manufacaturing, transportation, processing, or use) and from consumer uses of products containing the substance.

A considerable amount of attention has been given in recent years to the exposure of workers to chemical substances in occupational settings. A large body of information on occupational exposure to chemicals has been produced by the National Institute for Occupational Safety and Health (NIOSH). The key materials

produced by NIOSH are the National Occupational Hazard Survey, the NIOSH criteria documents, which recommend standards for occupational exposure to chemicals, and various reports dealing with exposure to substances in specific workplace settings. Included in the last group of reports are Health Hazard Evaluation Reports, the Industrial Hygiene Assessment Reports, and plant survey reports that are prepared by NIOSH and its contractors.

The National Occupational Hazard Survey (NOHS), a two-year field study initiated in 1972, was intended to describe the health and safety conditions in the American work environment and, more specifically, to determine the extent of worker exposure to chemical and physical agents. Briefly, the survey involved the visiting of approximately 5,000 business establishments in 67 metropolitan areas selected by the Bureau of Labor Statistics as representative of the non-agricultural businesses covered under the Occupational Safety and Health Act of 1970. Approximately 8,000 chemical substances and physical agents were identified as potential hazards during the survey. In the Exposure Aspects sections, EPA has presented the NOHS data, where available, on the total number of persons estimated to be potentially occupationally exposed to the substance in the United States. Where appropriate, a further breakdown of exposed population size by type of industrial activity or occupational category is presented.

Although the NOHS data base is an extremely valuable tool to gauge the extent of direct exposure to chemical substances in occupational settings, it has limitations which reduce its usefulness. Because the data were collected five to seven years ago, some may be obsolete. Furthermore, the data collection method relied almost exclusively on the observations of a surveyor who interviewed plant management and personnel and toured the premises of the plant noting the number of employees potentially exposed to certain materials. Although the survey

procedures were designed to minimize subjectivity by the surveyor, it is possible that some of the data reflect judgments made by the surveyor.

Another limitation of the NOHS is that certain types and some specific chemical facilities were excluded from the survey. Those excluded were either classified because of national defense security, engaged in agricultural production, mining (except oil and gas), or were private households. About 5,000 different facilities were surveyed, and the data were extrapolated to a nationwide scale.

The NIOSH criteria documents, which as stated above are intended to support NIOSH's recommended standards for occupational exposure to chemical substances and physical agents, have also been used by EPA in preparing the Exposure Aspects sections. These criteria documents usually present a review of the extent of occupational exposure, including information obtained from the NOHS survey, from historical reports appearing in the published literature, and from other investigations carried out by NIOSH. NIOSH also carries out industrial hygiene surveys and health hazard evaluations of specific plants and operations to determine the level of worker exposure to chemicals. Included in these investigations are actual sampling and analysis of the workplace environment.

In addition to information from NIOSH, EPA has also used clinical, historical and anecdotal reports from the published literature, and material submitted to EPA by industry under various provisions of TSCA.

The Exposure Aspects sections also reference the OSHA Occupational Safety and Health Standards, the NIOSH recommended standards, and/or the American Council of Government and Industrial Hygienists (ACGIH) threshold limit values (TLV's), whenever such information exists for the substance. The TLV, as defined by the ACGIH, is the airborne concentration of a substance to which it was believed at the time of its adoption that nearly all workers may be repeatedly exposed day after day

without adverse effect. Three categories of TLV's may be specified: (1) TLV-TWA (time-weighted average) - the average concentration for a normal 8-hour workday or 40-hour workweek; (2) TLV-STEL (short-term exposure limit)--the maximum concentration to which workers can be exposed for a period up to 15 minutes; and (3) TLV-C (ceiling)--the concentration that should not be exceeded even instantaneously. In 1971, OSHA adopted the ACGIH's TLV's for approximately 400 chemicals as the official federal standards for occupational exposure. Additional and revised standards are recommended to OSHA by NIOSH in the NIOSH Criteria Documents; these recommended standards are generally in the form of TLV's as described above. These TLV's and Occupational Safety and Health Standards for exposure do not reflect the actual levels of occupational exposure to these substances. They may, however, provide an indication of the upper limits of currently permitted exposure in most occupational settings (of course, full compliance with such standards may not always occur). Worker exposure may vary widely among different work assignments in a given plant and among different plants. It should also be pointed out that the TLV's are based on the health effects information existing at the time they were set and that they are revised as more data become available. Therefore, measurements showing that certain occupational exposures are at or below the TLV are not automatically accepted by EPA to mean that those exposures should not be of concern or are "safe."

2. Consumer

With respect to direct human exposure from the consumer use of products containing the substance, there is usually far less information available than for direct exposure in occupational settings. As stated earlier, the principal sources of information on the uses of a substance are various trade publications such as the Chemical Marketing Reporter, Chemical and Engineering News, reference works such as the Faith, Keyes, and Clark's Industrial Chemicals and the Condensed Chemical Dictionary. Typically, there is information available on the general function

of the substance (e.g., flame retardant, solvent or aerosol propellant), and less frequently on its specific applications (such as a flame retardant for children's clothing, a dry-cleaning solvent, or an aerosol propellant for shaving creams). Although there is usually some information available on the amount of the substance consumed annually in its different uses, the level of detail varies greatly from substance to substance, and even for a given substance, the level of detail may vary from one use to another. Measurement data are sometimes available from the Consumer Product Safety Commission (CPSC) on direct human exposure to a substance from its use in a consumer product. Usually it is necessary for EPA to rely upon a qualitative understanding of the product's use and to consider the substance's chemical and physical properties to gain some insight into the likelihood and potential magnitude of human exposure. As with occupational exposure, there are occasionally published reports of adverse human and animal health effects associated with the use (or often misuse) of the substance or a product containing it.

E. General Population Exposure

As explained earlier in this attachment, the term "general population exposure" is used for those circumstances of exposure involving the substance's entering the environment from its manufacture, processing, distribution in commerce, use, or disposal, and ultimately reaching humans through its presence in some environmental medium such as air, water, or soil. Assessment of this type of exposure is more difficult than that for consumer and occupational exposure because it requires the development of predictive techniques based on structure/activity relationships, laboratory data, physical/chemical properties and environmental transport phenomena. The difficulties occur in determining how laboratory data reflect the fate of the chemical in the environment and in accounting for how various properties (vapor pressure, solubility, sorption data, etc.) combine to determine the most probable transport and transformation of the chemical in the environment. For example, if a chemical is discharged to water,

the available data may indicate how much of the chemical volatilizes (evaporates into the air), how much goes into the sediment and how much dissolves in the water. The data may also be used, in some cases, to show the approximate quantity which may be taken up by organisms, such as plants or fish. The assessment may also determine how persistent the chemical is in the environment. That is, it may be possible to show whether the chemical is quickly degraded within or dispersed from some environmental medium or location or if there is a potential for it to accumulate.

Often, only qualitative assessments of environmental exposure can be made. These assessments primarily consist of identification of the probable environmental media where it appears that the chemical substance might accumulate and a rough calculation of the range of concentrations that may be found therein. Monitoring data, when available, may be used for verifying the validity of these assessments. These data are generally found in published literature and government reports. Basically, the reports indicate that the substance has been detected in samples taken from various media. The locations of the samples and the media are also identified. In many (but not all) cases, the concentration at which the substance was detected is also given. However, rarely does the data encompass all environmental media of interest.

Methods for making quantitative assessments of the environmental behavior of chemicals are being developed by EPA and will involve the use of mathematical models. However, until these models are developed and validated, monitoring data, where available, must be more heavily relied upon to identify potential environmental exposure. In some cases, there may be sufficient monitoring data to trace the progress of the substance from its source to the various environmental media in which it is found. Most often, however, the available monitoring data are not adequate for this, but rather provide an indication of the presence and/or concentration of the substance in a particular

place at a particular time. Those data may not reflect the impact of changes in discharges or environmental conditions nor the relative contribution of multiple sources to overall exposure. They may also reflect a condition (especially high or low concentration) which occurs infrequently, and therefore would not be an indication of normal environmental levels. However, keeping these limitations in mind, it may sometimes be possible to use these "snap-shot" monitoring data together with what is known about the manufacturing, processing, uses, etc., of the substance and its chemical and physical properties to reasonably describe the relationship(s) between the source(s) of the substance and its presence in the various environmental media.

Even in the absence of monitoring data showing the presence of a substance in the environment, it is possible to predict, at least qualitatively, whether a chemical will reach certain media by considering the chemical identity and form, sources and rates of expected environmental release, and the various chemical and physical properties that affect both its partitioning among various media, and its behavior within those media. Among the properties that are particularly useful, are the vapor pressure, which plays a major role in determining the exchange of a substance between the atmosphere and other environmental media, the solubility of the substance in water and factors that might influence its solubility such as pH and temperature, soil sorption properties, and the chemical, photochemical, and biological reactivity of the substance. It is also important to consider certain properties that indicate the potential of the substance to be taken up by organisms, to bioaccumulate and/or biomagnify in the food-chain. Knowledge of the structure of the substance, its tendency to form complexes with biological molecules and the relationship between fat and water solubility (usually measured as the octanol/water partition coefficient) allow reasonable predictions of the fate of the chemical to be made.

Once an estimate has been made of the environmental levels of the substance, population data along with appropriate life-style information can be combined to obtain an estimate of the potential level of exposure. If it is determined that the substance under study is discharged into a particular river and has the potential for accumulating in the fish in that river and, further, that the local population utilizes the fish as a food source, an estimate can be made of the amount of the chemical to which the population is exposed. There are three main factors used in assessing this exposure: amount, frequency, and duration. The environmental levels help determine the amount of a substance to which humans are exposed. It must then be determined how often contact (exposure) with a chemical occurs and how long the contact lasts. Duration may be difficult or impossible to measure for general population exposure. For occupational and consumer exposure, it is less difficult. Duration may be as long as a person is at his/her place of employment or the length of time it takes for a person to use a product. However, for a person consuming a contaminated fish, duration is difficult to determine. In a case like this, it may be assumed the duration is continuous. As far as frequency is concerned, an estimate may be made of how often the fish are consumed. Exposure may occur as a result of the discharge of the chemical to the air, resulting in local populations being exposed through inhalation. In this case, exposure occurs continuously over time.

When all of the factors described in this section are combined, an estimate may be made of general population exposure. The estimate may be in the form of the quantity of chemical a person may ingest or inhale over time, the concentration to which the person may be exposed during a number of incidents, or whatever form is appropriate to best describe how exposure occurs. Whether or not the exposure is likely to be hazardous to humans will be covered in a health effects assessment which follows the exposure assessment in each support document.

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